

## REMARKS

### I. Status of the Application

Claims 46-55, 61-76, 85, 86 and 90-92 are presently pending in the instant application. Applicants gratefully acknowledge the withdrawal of the rejections of claims 46-55, 61-76, 85 and 86 under U.S.C. § 112, first paragraph and of claims 48, 63-66 and 75 under 35 U.S.C. § 112, second paragraph. Claims 46-55, 62-71, 73-76, 85, 86 and 90-92 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Simone, U.S. Patent No. 5,397,786, in view of Thomas et al., U.S. Patent No. 5,972,985, Buchholz et al., U.S. Patent No. 6,514,973, and Hageman et al., U.S. Patent No. 6,420,342. Claim 72 remains rejected under 35 U.S.C. § 103(a) as being unpatentable over Simone in view of Thomas et al., Buchholz et al., and Kampinga et al., U.S. Patent No. 6,455,511, and further in view of Kuznicki et al., U.S. Patent No. 5,464,619.

Applicants have amended the claims under consideration to more clearly define and distinctly characterize Applicants' novel invention. Specifically, Applicants have amended claim 46 to recite "and wherein the fluid treats hypohydration when administered to a subject in need thereof." Support for this amendment can be found in the published application at least at paragraph [0027], where Applicants teach subjects, and at paragraph [0019], where Applicants teach treating hypohydration. The amendments presented herein contain no new matter.

Applicants respectfully request entry and consideration of the foregoing amendments, which are intended to place the case in condition for allowance or at least in better condition for appeal. The present Response After Final Rejection is being filed within 2 months of the mailing date of the Final Office Action. Accordingly, Applicants request issuance of an advisory action.

II. **Claims 46-55, 62-71, 73-76, 85 and 86 Are Nonobvious over Simone, Thomas et al., Buchholz et al. and Hageman et al.**

At page 3, section 7 of the Final Office Action, claims 46-55, 62-71, 73-76, 85, 86 and 90-92 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Simone, U.S. Patent No. 5,397,786, in view of Thomas et al., U.S. Patent No. 5,972,985, Buchholz et al., U.S. Patent No. 6,514,973, and Hageman et al., U.S. Patent No. 6,420,342. The Office Action states that Applicants' arguments are not found persuasive because statements of intended use or purpose do not limit the interpretation of the claim since the patentability of the product is not dependent on the manner in which the product is going to be ultimately used. The Office Action further states that, in response to Applicants' argument that there is no teaching or suggestion for the inclusion of sarcosine or dimethylglycine, the Examiner recognizes that sarcosine or dimethylglycine are art-recognized equivalents to betaine at the time the invention was made (as evidenced by Buchholz et al.), and that one of ordinary skill in the art would have found it obvious to substitute sarcosine or dimethylglycine for betaine.

Applicants respectfully traverse this rejection. The combination of cited references fail to teach or suggest Applicants' claimed invention.

Claim 46 and claims depending therefrom are directed in part to a fluid for treating hypohydration, comprising at least one methyl amine, one or more digestible carbohydrates and one or more minerals, wherein the methyl amine is selected from *dimethylglycine* and *sarcosine* and the fluid has an essentially hypotonic osmolarity in the range of 70 to 275 mOsm/l, and wherein the fluid *treats hypohydration when administered to a subject in need thereof*. Accordingly, a *physical characteristic* of the claimed fluid is that it is hypotonic and *treats hypohydration* when administered to a subject.

Applicants respectfully submit that, contrary to the assertions in the Office Action, one of skill in the art would not recognize that sarcosine or dimethylglycine could be substituted for betaine in a fluid that treats hypohydration. Although sarcosine, dimethylglycine and betaine are all methyl donors used for transmethylation, it is *not* the role of methyl donor that renders sarcosine and dimethylglycine particularly suitable for use in the present invention. Instead, it is their ability to act as *osmolytes* that renders them useful in a fluid that treats hypohydration. Although Buchholz teaches the use of methyl amines, it is for their use as *methyl donors* for transmethylation. *Nowhere* does Buchholz teach or suggest that sarcosine and dimethylglycine *act as osmolytes* or that their inclusion in a fluid that treats hypohydration. One of skill in the art, based on the teachings of Buchholz, would not appreciate that sarcosine and dimethylglycine would suitably function as osmolytes in a fluid that treats hypohydration.

Further, sarcosine and dimethylglycine have *physical characteristics* that *differ greatly* from those of betaine. These physical characteristics would lead one of skill in the art to believe that sarcosine and dimethylglycine would not be suitable for use in a fluid that treats hypohydration. For instance, betaine is much more readily soluble in alcohol than either dimethylglycine or sarcosine. Given that solubility determines to a large extent resorbability from the intestines and subsequent distribution throughout the body, and that insolubility promotes removal from the body, one of skill in the art would not recognize that dimethylglycine and sarcosine, with their poor solubilities, would function like readily soluble betaine. Specifically, given the poor solubilities of sarcosine and dimethylglycine, it is *quite surprising* that they are able to remain in the body to function in a variety of different cells as osmolytes. Certainly, one of skill in the art would not expect good osmolytic properties based on the solubility profiles of sarcosine and dimethylglycine.

Further, betaine is a quaternary amine, while dimethylglycine and sarcosine are tertiary and secondary amines, respectively. Quaternary amines are ionic and, as such, are good electrolytes. Electrolytes are well known as compounds that are beneficial in treating dehydration. In contrast, both sarcosine and dimethylglycine are nonionic. Thus, one of skill in the art would not look to dimethylglycine and sarcosine to function as electrolytes.

In addition, the metabolism of each of these compounds differs greatly with respect to time and circumstances within the body. For instance, betaine donates a methyl group the presence of betaine homocysteine methyltransferase, which is primarily present in the liver. In contrast, the dehydrogenases that interact with sarcosine and dimethylglycine are present both in the liver and in many other parts of the body, and require the presence of hydrogen acceptors and flavines. For at least these reasons, one of skill in the art would not conclude that sarcosine or dimethylglycine could readily be substituted for betaine in a fluid that treats hypohydration merely because each of these compounds can function as an electron donor.

Simone fails to teach or suggest each and every limitation of the claimed invention. Simone is directed to liquid compositions that can include membrane stabilizers such as choline chloride, betaine chloride and methionine (abstract). Simone does not teach or suggest the use of dimethylglycine or sarcosine, a hypotonic solution that treats hypohydration when administered to a subject, or a hypotonic osmolarity in the range of 70 to 275 mOsm/l, as claimed by Applicants.

Thomas et al. fails to cure the deficiencies of Simone. Thomas et al. is directed to nutriceutical compositions useful as dietary supplements (abstract). Thomas fails to teach a composition including sarcosine or dimethylglycine, a hypotonic solution that treats hypohydration when administered to a subject, or Applicants' claimed osmolarity of between 70 and 275 mOsm/l.

Buchholz et al. fails to cure the deficiencies of Simone and Thomas et al. As discussed above, Buchholz et al. is directed to compositions for the treatment and prevention of *transmethylation disorders* such as neurological and pathophysiological diseases (column 1, lines 4-9), not for the treatment of hypohydration. Buchholz et al. teaches that a decrease of the pool of methyl donors and/or of methyl transporters may lead to transmethylation disorders (column 3, lines 26-27), and teaches that methyl donors include methionine, S-adenosylmethionine, choline, methylglycine, dimethylglycine and trimethylglycine (column 3, lines 6-8). Thus, the methyl amines taught by Buchholz are in the context of treating a transmethylation disorder. Nowhere does Buchholz et al. teach or suggest that dimethylglycine or sarcosine can be used in a fluid that *treats hypohydration* when administered to a subject. In fact, for at least the reasons set forth above, one of skill in the art would fail to recognize, based on the teachings of Buchholz et al., that dimethylglycine or sarcosine would be useful in a fluid that treats hypohydration. Indeed, Buchholz et al. is completely silent with respect to hypohydration in general and fluids for treating hypohydration in particular. In addition, Buchholz et al. fails to teach or suggest a hypotonic fluid, let alone a hypotonic fluid having a specific osmolarity such as between 70 and 275 mOsm/l, as claimed by Applicants.

Hageman et al. fails to cure the deficiencies of Simone, Thomas et al. and Buchholz et al. Hageman et al. is directed to nutritional preparations including ribose and folic acid to support total nucleotide metabolism (column 5, lines 8-12). Hageman et al. neither teaches nor suggests a composition including sarcosine or dimethylglycine. Further, Hageman et al. does not teach or suggest fluids for treating hypohydration, hypotonic fluids, or an osmolarity of 70 to 275 mOsm/l, as claimed by Applicants.

Thus, the cited references, alone or in combination, fail to render the claimed invention obvious. Accordingly, Applicants respectfully request that the rejection of claims 46-55, 62-71, 73-76, 85, 86 and 90-92 under 35 U.S.C. § 103(a) as being unpatentable over Simone, in view of Thomas et al., Buchholz et al. and Hageman et al., be reconsidered and withdrawn.

**III. Claim 72 Is Nonobvious over Simone in View of Thomas et al., Buchholz et al. and Kampinga et al., further in View of Kuznicki et al.**

At page 7, section 5 of the instant Office Action, claim 72 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Simone in view of Thomas et al., Buchholz et al. and Kampinga et al., U.S. Patent No. 6,455,511, and further in view of Kuznicki et al., U.S. Patent No. 5,464,619. The Office Action states that the cited references in combination make clear that the use of caffeine in rehydration solutions is old and well known, and that the combination of references makes clear that the formulation containing dimethylglycine, one or more digestible carbohydrates (e.g., glucose, fructose, galactose, mannose, ribose and inositol), minerals, caffeine, glycerol and vitamins are old and well known. The Office Action is silent as to why Kampinga et al., in combination with the other cited references, would render the claimed invention obvious.

Applicants respectfully traverse this rejection. Applicants respectfully submit that the combination of cited references fails to render claim 72 obvious. The teachings of Simone, Thomas et al. and Buchholz et al. are described above.

Kampinga et al. fails to cure the deficiencies of Simone, Thomas et al. and Buchholz et al. Kampinga et al. is directed to compositions for sports beverages containing trehalose. (column 1, lines 11-15). Kampinga et al. fails to teach or suggest a fluid including sarcosine or dimethylglycine that treats hypohydration.

Kuznicki et al. fails to cure the deficiencies of Simone, Thomas et al., Buchholz et al. and Kampinga et al. Kuznicki et al. teaches a beverage that has enhanced cellular hydration and drinkability due to a specific combination of green tea solids, electrolytes and carbohydrates (column 1, lines 10-14). Kuznicki et al. fails to teach or suggest a fluid including sarcosine or dimethylglycine that treats hypohydration.

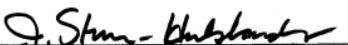
Thus, the combination Accordingly, the combination of Simone in view of Thomas et al., Buchholz et al. and Kampinga et al., further in view of Kuznicki et al. fails to render claim 72 obvious. Thus, Applicants respectfully request that this rejection be reconsidered and withdrawn.

#### IV. Conclusion

Reconsideration and allowance of all the pending claims is respectfully requested. If a telephone conversation with Applicants' attorney would expedite prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 720-9600. The Commissioner is hereby authorized to charge any additional fees or credit overpayment to Deposit Account No. 19-0733.

Respectfully submitted,

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